AUG 26 2005

K052101

510(k) Summary – C.f.a.s. (Calibrator for Automated Systems) HbA1c

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa M. Ambrose

Date prepared: August 2, 2005

Device name

Proprietary name: C.f.a.s. (Calibrator for Automated Systems) HbA1c

Common name: calibrator for Hemoglobin measurements

Classification name: Calibrator for hemoglobin or hematocrit measurement

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Device description

C.f.a.s. HbA1c is single-level lyophilized calibrator based on hemolyzed sheep blood and human blood. The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers. During use, calibrator dilutions are prepared automatically on-board the analyzer resulting in six levels.

Intended use

C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Predicate device

We claim substantial equivalence to the calibrator included in the Tina-Quant HbA1c reagent kit, originally cleared under K934070.

C.f.a.s. HbA1c is identical to this calibrator; however, it is now being provided at a single-level and sold as a separate product.

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510(k) Summary – C.f.a.s. (Calibrator for Automated Systems) HbA1c, Continued

Substantial equivalency – similiarities

The table below indicates the similarities between the modified C.f.a.s. (Calibrator for Automated Systems) HbA1c and its predicate device (calibrator in Tina-Quant HbA1c test system, K934070).

Characteristic	Predicate calibrator	C.f.a.s. HbA1c
Intended Use	Calibrator included in kit for calibration of the quantitative Tina-Quant HbA1c method.	C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.
Format	Lyophilized	Same
Matrix and composition	Hemolysate derived from human and sheep blood; 0.9% TTAB (tetradecyltrimethylammonium bromide); stabilizers	Same

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510(k) Summary – C.f.a.s. (Calibrator for Automated Systems) HbA1c, Continued

Substantial equivalency – differences

The table below indicates the differences between the modified C.f.a.s. (Calibrator for Automated Systems) HbA1c and its predicate device (calibrator in Tina-Quant HbA1c test system, K934070).

Characteristic	Predicate calibrator	C.f.a.s. HbA1c
Handling	Reconstitute with 1.0 mL distilled or deionized water.	Reconstitute with 2.0 mL distilled or deionized water.
Levels	Four levels	Single level
Stability	Unopened: stable up to the expiration date Reconstituted: 2 days @ 2-8 °C 8 hours @ 20-25 °C 3 months @ -20 °C	Unopened: same Reconstituted: 2 days @ 2-8 °C 8 hours @ 15-25 °C 3 months @ (-15) to (-25) °C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 26 2005

Theresa M. Ambrose. Ph.D., RAC
Regulatory Principal
Roche Diagnostics
Centralized Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k052101
Trade/Device Name: C.f.a.s. (Calibrator for Automated Systems) HbA1c
Regulation Number: 21 CFR 864.8165
Regulation Name: Calibrator for hemoglobin or hematocrit measurement
Regulatory Class: Class II
Product Code: KRZ
Dated: August 2, 2005
Received: August 3, 2005

Dear Ms. Ambrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052101

Device Name: **C.f.a.s. (Calibrator for Automated Systems) HbA1c**

Indications For Use:

C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052101